CMR

ORIGINAL

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF PENNSYLVANIA

UFCW LOCAL 1776 AND PARTICIPATING EMPLOYERS HEALTH AND WELFARE FUND, on behalf of itself and all others similarly situated

Plaintiff,

vs.

SMITHKLINE BEECHAM CORPORATION d/b/a GLAXOSMITHKLINE and GLAXOSMITHKLINE, PLC

Defendants.

CIVIL ACTION
MDL No. 1871
07-md-01871

CLASS ACTION COMPLAINT

DEMAND FOR JURY TRIAL

FILED
MAY 21 2010
MICHAEL E. KUNZ, Clerk
By_____Dep. Clerk

10 2475

CMR

CLASS ACTION COMPLAINT

UFCW Local 1776 and Participating Employers Health and Welfare Fund ("UFCW Fund") ("Plaintiff"), on behalf of itself and all others similarly situated, brings this action against Defendants GlaxoSmithKline PLC through its subsidiary, SmithKline Beecham Corporation d/b/a GlaxoSmithKline, seeking damages and other monetary relief. Plaintiff makes the allegations of this Complaint based upon personal knowledge as to matters relating to itself, and upon investigation of counsel and information and belief as to all other matters.

NATURE OF THE ACTION

1. This complaint stems from Defendants' scheme to market and promote Avandia® (rosiglitazone maleate), Avandamet® (a combination of rosiglitazone maleate and metformin) and Avandaryl® (a combination of rosiglitazone maleate and glimepiride), (collectively, "Avandia"), which are medications indicated to treat Type II diabetes mellitus. Defendants' marketing scheme has included deliberately concealing, suppressing and affirmatively

misrepresenting the significant safety risks associated with the use of Avandia, including but not limited to, heart attack, heart failure, or other heart-disease related risks.

2. Defendants marketed and promoted Avandia as a safe and effective means of enabling the body to utilize naturally secreted insulin and to control blood sugar levels in individuals with Type II diabetes mellitus. However, published findings from 1999—the year Avandia was approved by the FDA for sale in the U.S.—including a study from The New England Journal of Medicine, strongly indicated that studied groups of Avandia users incurred a 43 percent greater risk of heart attacks than those taking other competing diabetes medications, or diabetics taking no medications. Further, the researchers found that patients incurred a 64 percent increased risk of dying from heart attacks or heart-related diseases while taking Avandia.

3. At a congressional hearing held on Wednesday, June 6, 2007, Commissioner Andrew von Eschenbach of the U.S. Food and Drug Administration ("FDA") revealed that the FDA was ordering Defendants to add a "black box" warning to Avandia, strengthening existing warnings regarding the use of Avandia related to an increased risk of developing congestive heart failure ("CHF"), a condition in which the heart does not adequately pump blood. The FDA found that the warnings previously issued by Defendants, advising Avandia users to simply consult their doctors about the continuous use of Avandia, were inadequate to protect such users.

4. On July 30, 2007, two FDA advisory panels, the Endocrine and Metabolic Advisory Committee and the Drug Safety and Risk Management Advisory Committee, met to evaluate Avandia and similar antidiabetic drugs. The panels recognized the increased risk for heart attacks posed by Avandia and voted overwhelming, 20-3, urging the FDA to consider raising its warning level to black-box status or implementing a patient registration program. On

August 14, 2007, the FDA increased the warning for Avandia's increased risk of heart failure, and the following black box warning was added to the label:

> Thiazolidinesdiones, including rosiglitazone, cause or exacerbate congestive heart failure in some patients (see WARNINGS). After initiation of AVANDIA, and after dose increase, observe patient carefully for signs and symptoms of heart failure (including excessive, rapid weight gain, dyspnea, and/or edema). If these signs and symptoms develop, the heart failure should be managed according to current standards of care. Furthermore, discontinuation or dose reduction of AVANDIA must be considered.
>
> AVANDIA is not recommended in patients with symptomatic heart failure. Initiation of AVANDIA in patients with established NYHA Class III or IV heart failure is contraindicated. (See CONTRAINDICATIONS and WARNINGS.)

5. Thereafter, on November 19, 2007, the FDA added a second black box warning for Avandia's increased risk of heart attacks and other myocardial ischemic events, and the following language was added to the black box warning:

> WARNING: CONGESTIVE HEART FAILURE AND MYOCARDIAL ISCHEMIA
>
> A meta-analysis of 42 clinical studies (mean duration 6 months; 14,237 total patients), most of which compared AVANDIA to placebo, showed AVANIDA to be associated with an increased risk of myocardial ischemic events such as angina or myocardial infarction. Three other studies (mean duration 41 months; 14,067 patients), comparing AVANDIA to some other approved antidiabetic agents or placebo, have not confirmed or excluded this risk. In their entirety, the available data on the risk of myocardial ischemia are inconclusive.

6. Most recently, in February 2010, the United States Senate Finance Committee released a report concluding, among other things, that:

> The totality of evidence suggests that GSK was aware of the possible cardiac risks associated with Avandia years before such evidence became public. Based on this knowledge, GSK had a duty to sufficiently warn patients and the FDA of its concerns in a timely manner. Instead, GSK executives intimidated independent physicians, [and] focused on strategies to minimize findings that Avandia may increase cardiovascular risk ...

Rather than issue proper warnings and provide accurate information about Avandia's risks and benefits, Defendants chose instead to keep their deceptive propaganda and marketing machine running full steam ahead and never took any affirmative steps to correct the misinformation and deceptive advertising scheme that it had and continued to perpetrate, ensuring that it would continue to maximize the prescription and sale of Avandia so long as consumers, Third-Party Payors, prescribing doctors, and the medical and healthcare community remained unaware of Avandia's true risks.

7. Defendants knew or should have known that Avandia was unsafe as compared to other diabetes medications. Moreover, Defendants knew or should have known that Plaintiff and the Class would be injured to the extent they must pay for Avandia and the health care services and facilities resulting from heart-related injuries associated with Avandia's use. As a result of Defendants' failure to adequately warn consumers, Third-Party Payors, prescribing doctors, and the medical and healthcare community that the use of Avandia creates a roughly 50% greater risk of heart attack and heart disease-related death, Plaintiff and the Class were denied the opportunity to make fully informed decisions about whether and how to include Avandia on their formularies and paid for more prescriptions than they otherwise would have paid for and/or paid for Avandia that would have been sold at a lower price had market forces been allowed to operate unfettered by Defendants' violations.

8. In addition to the resulting personal injuries, unnecessary deaths, and the profound implications for public health, the financial toll that Defendants' false and deceptive marketing of Avandia has had on Plaintiff and the Class has been dramatic. Relying upon Defendants' promises of superior treatment and better cardiovascular outcomes compared with the older diabetes drugs, third-party payors of Avandia have paid a hefty premium. Defendants'

omissions of, and deliberate misrepresentations related to, critical information regarding the serious health risks associated with Avandia have caused financial harm to Plaintiff and the Class, who hereby seek compensatory, punitive and statutory damages, injunctive relief to prevent Defendants from continuing their unlawful activities, reasonable attorneys' fees and such other just relief as the Court may award.

PARTIES

9. Plaintiff UFCW Local 1776 and Participating Employers Health and Welfare Fund ("UFCW Fund") is a citizen of the Commonwealth of Pennsylvania, and has its principal place of business at 3031B Walton Road, Plymouth Meeting, Montgomery County, Pennsylvania. UFCW Fund is an "employee welfare benefit plan" and an "employee benefit plan" as defined in Employee Retirement Income Security Act (ERISA), 29 USC §§ 1002(1), 1002(3), 1003(a). As such, UFCW Fund is a legal entity entitled to bring suit in its own name pursuant to 29 USC § 1132(d). UFCW Fund is a not-for-profit-trust, sponsored by and administered by a Board of Trustees, established and maintained to provide comprehensive health care benefits to participant-workers, who are employed under various collective bargaining agreements, and to their dependents.

10. UFCW Fund's participant-workers are members of the United Food and Commercial Workers Union, Local 1776, which represents 24,000 members who work in southeast, northeast and central Pennsylvania, northeast Maryland and southern New York in supermarkets, drug stores, food processing plants, government services, manufacturing facilities, nursing homes, professional offices and Pennsylvania's Wine and Spirits Shops.

11. UFCW Fund has paid all or part of the cost of its participants' purchases of Avandia during the Class Period, as defined herein. Pursuant to its plan, Plaintiff, through a

pharmacy benefit manager ("PBM") and a third-party administrator, purchased prescription drugs for its participants and provided coverage for medical testing and visits to physicians. Each plan participant has a prescription drug plan identification card which he/she presents at a participating pharmacy. The pharmacy collects a co-payment from the participant and bills the UFCW Fund (through a prescription benefit manager) for the remaining cost of Avandia purchases. Avandia prescriptions would have been restricted or priced differently if the FDA, Plaintiff's PBM and/or prescribers had truthful and complete information about the drug. Plaintiff has been injured as a result of the unlawful conduct of Defendant as alleged herein.

12. Defendant GlaxoSmithKline PLC ("GSK PLC") is a United Kingdom corporation with its principal place of business at 980 Great West Road, Brentford, London Middlesex TW8 9 GS, United Kingdom. GSK PLC either directly or through its wholly-owned subsidiaries, designs, produces, markets and promotes the drugs Avandia, Avandamet and Avandaryl in Pennsylvania and nationwide. Defendant GlaxoSmithKline USA is a wholly-owned subsidiary of GSK PLC. At all relevant times, GSK PLC acted by and through its agents, servants, workers, employees, officers and directors, all of whom were acting in the course and scope of their actual and apparent authority, agency, duties or employment.

13. Defendant SmithKline Beecham Corporation d/b/a GlaxoSmithKline (GSK USA) is a Pennsylvania corporation with its principal place of business at One Franklin Plaza, P.O. Box 7929, Philadelphia, Pennsylvania. GSK USA designs, produces, markets and promotes the drugs Avandia, Avandamet and Avandaryl in Pennsylvania and nationwide. GSK USA is a whollyowned subsidiary of GSK PLC. At all relevant times, GSK USA acted by and through its agents, servants, workers, employees, officers and directors, all of whom were acting in the course and scope of their actual and apparent authority, agency, duties or employment.

14. Defendant, GSK USA along with defendant GSK PLC conducts substantial business in Philadelphia, Pennsylvania, including the sale and distribution of Avandia and has sufficient contacts with Pennsylvania or otherwise intentionally avails itself of the laws and markets of Pennsylvania, so as to sustain this Court's jurisdiction over Defendants.

JURISDICTION AND VENUE

15. This Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1332 (d)(2), which provides federal district courts with original jurisdiction over civil actions in which the matter in controversy exceeds the sum or value of $5,000,000, exclusive of interest and costs, and is a class action in which "any member of a class of Plaintiffs is a citizen of a state different from any defendant."

16. This Court has further jurisdiction over this action pursuant to the Class Action Fairness Act, because at least one member of the Class is a citizen of a different state than the Defendants and the aggregate amount in controversy exceeds $5,000,000.00, exclusive of interest and costs.

17. Venue is proper in this District under 28 U.S.C. §1391 because Defendants engaged in substantial conduct relevant to Plaintiff's claims within this District, and have caused harm to Plaintiff and Class members residing within this District. Defendants received substantial compensation from the sales of Avandia in this District, and Defendants made misrepresentations and material omissions about Avandia in this District.

FACTUAL ALLEGATIONS

I. Avandia's Factual Background

18. Type 2 diabetes, the most common form of diabetes, results from the body's failure to produce enough insulin (insulin deficiency) and/or inability to use insulin properly

(insulin resistance). Insulin is necessary to process and remove blood sugar. Without insulin, sugar builds up in the bloodstream and cells are starved for energy. This can cause tissue breakdown, which can lead to numerous health dangers, such as kidney failure, blindness, and amputations. Furthermore, diabetics are at an increased risk, as compared to non-diabetics, for atherosclerosis, heart attacks, strokes, kidney disease, and nervous system damage. Thus, drugs designed to treat diabetes must be sensitive to, among other things, diabetics' preexisting cardiovascular risks.

19. The "first line" of treatment for Type 2 diabetes consists of established and inexpensive oral medications, primarily sulfonylureas and metformin. Indeed, metformin is recognized as the "gold standard" in Type 2 diabetes treatment. In its "Standards of Medical Care in Diabetes 2009," the American Diabetes Association noted that the consensus for treating Type 2 diabetes begins with "intervention at the time of diagnosis with metformin in combination with lifestyle changes and continuing timely augmentation of therapy with additional agents (including early initiation of insulin therapy) as a means of achieving and maintaining recommended levels of glycemic control." Metformin reduces the amount of sugar released by the liver between meals, promotes weight loss, and reduces cholesterol and triglycerides levels. Its side effects are minimal and include nausea and upset stomach. Sulfonylureas stimulate the pancreas to produce more insulin. Sulfonylureas combine well with other diabetes drugs for maximum effect on blood sugar; their side effects include hypoglycemia (low blood sugar) and weight gain. As a diabetic's disease progresses, medications may be added to the patient's regimen, including the use of insulin.

20. In the 1990s, pharmaceutical companies developed, manufactured and produced a class of drugs known as thiazolidinediones (TZDs). TZDs enable the body to more effectively use insulin by reducing insulin resistance in the body.

21. At all times material hereto, the TZD preparations available in the marketplace included Avandia (rosiglitazone), Avadamet (rosiglitazone and metformin), Avandaryl (rosiglitazone and glimepiride), Actos® (pioglitazone) and Actosplus® met (pioglitazone and metformin).

22. Avandia was approved by the FDA on May 25, 1999 as an oral antidiabetic agent which acts primarily by increasing insulin sensitivity. Avandia is recommended and prescribed for the management of Type II diabetes mellitus, also non-insulin-dependent diabetes mellitus ("NIDDM") or adult-onset diabetes. Type II diabetes is a serious and life threatening disease that affects about 18 to 20 million Americans. Avandia has been used by millions of individuals in the United States.

23. Avandamet was approved by the FDA on October 10, 2002 as a combination of Avandia and metformin in one single pill and is also recommended to treat NIDDM.

24. Avandaryl was approved by the FDA on November 23, 2005 as a combination of Avandia and glimepiride in one single pill and also recommended to treat NIDDM.

25. Since 1999, the FDA has been monitoring several heart-related adverse events (e.g. fluid retention, edema, and congestive heart failure ("CHF")) based on signals seen in controlled clinical trials and from post-marketing reports.

26. Despite the fact that Avandia lowers blood glucose levels in Type II diabetes patients, numerous studies have shown that use of Avandia dramatically increases the risk of cardiovascular events in Type II diabetes patients. Nevertheless, Defendants assured physicians

that these studies only illustrate a very slight increase in Low-density lipoprotein, "bad cholesterol" or LDL levels, and continued to falsely and fraudulently promote Avandia as a superior, effective, and safe drug for diabetic patients.

27. In 2001, the FDA requested that Defendants make a change to Avandia's prescribing label to warn doctors that the drug could cause fluid retention. However, shortly after, Defendants' sales representatives gave oral presentations at a medical convention denying the existence of serious risks associated with Avandia. The FDA responded with a letter to Defendants warning that the sales representatives and marketers should stop denying or minimizing the risks of heart attacks and heart-related diseases in patients.

28. In 2005, according to a June 1, 2007 *Bloomberg* article, Defendants performed a review and found that Avandia raised the risk of heart attacks by 31 percent. Defendants gave the information to the FDA and included the information on its website amid more than 2,000 studies, but Defendants did not highlight the information. Defendants state that the heart-risk studies, including Defendants' own, are flawed and they are not obligated, or legally required, to highlight every study done on its drugs. Defendant GSK PLC Chief Executive Officer Jean-Pierre Garnier told reporters at the company's annual meeting on May 23, 2007 in London, "Why would you publicize it . . .We don't publicize every submission we make to the Food and Drug Administration."

29. In April 2006, the FDA required labeling for Avandia to be updated to include new data in the WARNINGS section about a potential increased incidence of heart attack and heart-related chest pain in some patients. This change was based on the results of a controlled clinical trial in patients with existing CHF. A higher number of heart attacks or angina was observed in patients treated with Avandia compared to those treated with a placebo.

30. Thereafter, using published literature, the FDA website and a clinical trials registry maintained by Defendants, Steven E. Nissen, M.D., and Kathy Wolski, M.P.H. tabulated and compiled a meta-analysis of Avandia clinical studies with a duration of longer than 24 weeks, using randomized control groups not receiving Avandia, and having available the outcome data for myocardial infarction and death from heart attacks and heart-related diseases. Dr. Nissen and Dr. Wolski used 116 potentially relevant studies, and 42 trials that met the inclusion criteria. The study, published in The New England Journal of Medicine, revealed that Avandia was associated with a significant increase in the risk of myocardial infarction and with an increase in the risk of death from heart attacks and heart-related diseases that had borderline significance. Some have hinted that Dr. Nissen's loyalties were to Defendants' competitors since Dr. Nissen is leading a clinical trial studying Avandia's rival drug, Actos. However, Dr. Nissen has consulted in the past for Defendants on other matters. Moreover, Dr. Nissen gives drug-industry payments to charity. Nevertheless, instead of a responsible and reasoned response to this study, Defendants took steps to encourage aggressive dispensation of Avandia for persons to whom it posed grave health dangers.

31. Having obtained a leaked copy of the Nissen paper, Defendants prepared for its release in advance, and subsequent to its publication, Defendants engaged in a massive publication and advertising campaign designed to sway physician and consumer confidence. This marketing campaign consisted of advertisements, promotional literature for the offices of doctors and other health care providers, and other promotional materials to be provided to potential users of Avandia. Despite knowledge of the widespread health dangers of Avandia, Defendants failed to effectively warn consumers about the use of this drug as compared to other diabetes medications which posed much lesser health risks.

32. On May 21, 2007, the FDA issued a new safety alert that addressed potential safety issues stemming from the pooled analysis of previously completely controlled clinical trials demonstrating a significant increase in the risk of heart attack and heart-related diseases in patients treated with Avandia.

33. On May 23, 2007, consistent with recommendations made by senior FDA staff at an internal regulatory briefing held in April 2007, the FDA issued letters to Defendants requesting that Avandia's product labeling include a boxed warning to more prominently address the risks of heart failure associated with the use of Avandia.

34. On and around June 5, 2007, Defendants took out full-page ads in newspapers such as the *Washington Post* and *The New York Times* speaking directly to the consumers of Avandia.

35. On June 6, 2007, the FDA announced a meeting to be held on July 30, 2007 to discuss the risk of heart attacks and heart-related disease associated with thiazolidinediones, with a focus on Avandia, as presented by the FDA and Defendants.

36. On July 30, 2007, two FDA advisory panels, the Endocrine and Metabolic Advisory Committee and the Drug Safety and Risk Management Advisory Committee, met to evaluate Avandia and similar antidiabetic drugs. The panels recognized the increased risk for heart attacks posed by Avandia and voted overwhelming, 20-3, urging the FDA to consider raising its warning level to black-box status or implementing a patient registration program.

37. On August 14, 2007, the FDA increased the warning for Avandia's increased risk of heart failure to a black box warning.

38. Despite such overwhelming evidence, Defendants still insisted and insist to this day that Avandia does not increase the risk of heart attack. "We don't believe that a warning

about heart attack should be on the label," states Dr. Andy Zambanini, the company's director of clinical development.

39. Notwithstanding Defendants' refusal to acknowledge the dangers of Avandia, on November 14, 2007, the FDA issued its toughest warning against Avandia linking it to heart attacks and a second black box warning was added to the Avandia label warning of the increased risk of heart attacks and other myocardial ischemic events.

40. Since its introduction, Avandia has come to be used on a regular basis by millions of individuals worldwide, including at least one million in the United States. Avandia was Defendants' second best-selling product in 2006, generating revenues of $1.4 billion, with a further $246 million generated from the combination products Avandamet and Avandaryl. A one-month supply of Avandia sells for between $90 and $170. Consumers either paid for the drug completely out of pocket or paid their co-pay. The typical third-party payor co-payment was approximately $135-$140. This represented a dramatic increase in third-party payors' costs of drug therapy for Type II diabetes patients. Previously, the most prevalent oral drug therapy for Type II diabetes had been metformin, which had a typical retail price for a one-month prescription of approximately $45-$55, of which the typical third-party payor co-payment was approximately $50.

II. Approval, Labeling, and Promotion of Pharmaceuticals Marketed in the United States

41. Pursuant to the Federal Food, Drug and Cosmetic Act ("FDCA"), a pharmaceutical must be approved by the Food and Drug Administration ("FDA") before it is transported or distributed across state lines. *See* 21 C.F.R. § 301; *see also* 21 U.S.C. § 331. The Center for Drug Evaluation and Research is a division of the FDA and conducts limited research in the areas of drug quality, safety, and effectiveness.

42. In order for the FDA to approve a drug, the manufacturer must show that a drug is "safe for use" and effective for all "conditions prescribed, recommended, or suggested" on a drug's label. *See* 21 C.F.R. § 99.103; *see also* 21 C.F.R. §201.5.

43. Because the FDA will only find a drug product to be safe and effective if the proposed use is supported by well-designed, placebo-controlled clinical trials that establish a causal relationship to a statistically significant degree, a statement that a drug is "effective" or "works" or "has been proven to . . ." is understood to mean that well controlled clinical studies support the use. To make such a statement without such clinical trial proof is misleading. Further, failure to inform physicians that no placebo controlled clinical trials support a representation of drug efficacy is a violation of a pharmaceutical company's obligation to disclose. *See* 21 C.F.R. § 99.205.

44. The FDA allows pharmaceutical manufacturers to provide information for dissemination to health care practitioners, pharmacy benefit managers, health insurance issuers, group health plans, and Federal and State government agencies after a submission of an application to the FDA, if such information is fair and balanced and under the following circumstances:

- The information concerns a drug that has been approved, licensed and cleared for marketing by the FDA;
- The information is in the form of an unabridged copy of a peer-reviewed scientific or medical journal article or reprint, or an unabridged reference publication that pertains to a clinical investigation involving the drug and that is considered scientifically sound by experts who are qualified to evaluate the product's safety or effectiveness;
- The information does not pose a significant risk to the public health;
- The information is not false or misleading; and

- The information is not derived from clinical research conducted by another manufacturer, unless permission is received from that manufacturer. *See* 21 C.F.R. § 201.6(a). *See also* 21 U.S.C. § 360aaa.

III. Alternatives to Avandia

45. Physicians are free to prescribe FDA-approved drugs as they see fit to treat any condition or symptom for their patients. The medical community generally encourages physicians to prescribe the safest, most effective and cost-efficient treatment for their patients. Research and studies have illustrated that physicians can prescribe safer and/or equally effective alternatives to treat diabetes other than Avandia.

46. Another prescription medication for Type II diabetes mellitus is pioglitazone (Actos®), a drug manufactured and promoted by Takeda Pharmaceuticals North America.

47. On March 15, 2000, Dr. John B. Buse of the University of North Carolina School of Medicine, the incoming president of the American Diabetes Association, wrote Dr. Jane Henney, the Commissioner at the FDA stating that "the frequency of mild and serious adverse events that I have seen with troglitazone [Rezulin®] and pioglitazone [Actos®] is comparable to or less than the number I have observed with other antidiabetic agents." Rezulin was withdrawn from the U.S. market on March 21, 2000. Dr. Buse strongly suggested that Actos is one of the most effective, safe and beneficial drugs in its class and Avandia may be associated with less beneficial cardiac effects or even adverse cardiac outcomes.

48. A prospective, randomized trial of cardiovascular outcomes, called Prospective Pioglitazone Clinical Trial in Macrovascular Events (PROACTIVE) shows lower cardiac risks with Actos. The trial examines whether the observed risks of Avandia represent a "class effect" of thiazolidinediones. Actos was studied, and the primary end point, a broad composite that included coronary and peripheral vascular events, showed a beneficial trend with the use of Actos (hazard ratio, 0.90; P=0.095). A secondary end point consisting of myocardial infarction,

stroke, and death from any cause showed a significant effect favoring Actos (hazard ratio, 0.84; P=0.027). Notably, Actos appears to have more favorable effects on lipids, particularly triglycerides, than does Avandia.

49. Additionally, a June 23, 2007 *Bloomberg* article discusses a study that found that Actos may lower the risk of heart attack and death by 44 percent in diabetic patients with kidney disease. The findings, from a subgroup of patients enrolled in a previous study, were reported at the June 23, 2007 meeting of the America Diabetes Association in Chicago. In a separate study, Actos reduced inflammation and blood clots more than a placebo. Thus, Actos may have fewer cardiac risks than Avandia and prove to be a safer alternative to Avandia for the treatment of Type II diabetes mellitus.

50. However, physicians have been misled by Defendants to believe that Avandia is superior in its effectiveness and safety to other equally effective and safer alternatives like Actos. As a result of Defendants widespread misleading marketing and promotion of Avandia's superior safety and effectiveness over safer and equally effective alternative drugs like Actos, many physicians are less inclined to prescribe patients these alternatives antidiabetic drugs.

51. Yet a June 18, 2007 *USA Today* article discusses an increased number of physicians discontinuing Avandia prescriptions and are instead prescribing Actos as an alternative to the diabetes medication. "Before the journal [*The New England Journal of Medicine*] posted the study May 21, U.S. doctors were writing about 240,000 prescriptions [of Avandia] per week, Glaxo spokeswoman Alice Hunt says. That has dropped to about 215,000 to 220,000 per week. Glaxo estimates the number of people taking Avandia have dropped from about 1 million to 900,000 in the USA." Additionally, new prescriptions for Avandia dropped 40% as a result of Dr. Nissen's study. New prescriptions are defined as the first prescription a

doctor writes for a patient who might already have been taking Avandia under a different doctor's care. "Prior to Nissen's study, U.S. doctors wrote about 80,000 new Avandia prescriptions weekly; that number has dropped to about 55,000, Hunt says." The *USA Today* article explains that physicians are switching patients to Actos as an alternative.

52. Most recently, another study conducted by researchers at Harvard University and published in February 2010 in the journal of the American Diabetes Association, Diabetes Care, found that Avandia increases a diabetic's heart attack risk by 30% compared with the older diabetes drug sulfonylurea. And when compared with metformin, Avandia increases a diabetics' heart attack risk by 120%.

IV. Defendants' Marketing and Promotion of Avandia as Safe and Effective

53. From its product launch to the present, Defendants engaged in widespread fraudulent statements and conduct, and pervasive false and misleading marketing, advertising and promotion of Avandia, spending hundreds of millions of dollars to further these efforts. Defendants deceived physicians, consumers and others in the medical community regarding the comparative efficacy of Avandia to other medications designed to control Type II diabetes mellitus. Defendants failed to warn – and affirmatively misled physicians, consumers, Third-party Payors, and others in the medical community regarding Avandia's association with increased risk of heart attacks and heart-related diseases.

54. Defendants were required to provide fair and balanced information whenever they engaged in promotional activities. Promotional activities encompass not only written material but all presentations. Defendants knew that whenever they were required to provide fair and balanced information, they were required to provide any negative information as well as positive information about their drug.

55. Since 1999 Defendants have spent millions on Direct-to-Consumer ("DTC") print and television advertising, aimed at convincing patients to request Avandia from their doctors. Defendant's marketing campaign also targeted doctors as well as the individuals and groups responsible for selecting the drugs covered by health coverage plans and included on pharmacy formularies. Defendants sought to influence these targets through, among other tactics, print media, misleading promotional materials, lavish company-sponsored dinners, and "conferences" at posh resorts. Defendants produced and distributed "studies" whose sole purpose was to advance the company's marketing message and which were intended to, and did, deceive diabetics, medical professionals, and the general public. Defendants also employed sales representatives who spread the Avandia message by calling on thousands of physicians throughout the country, paid speakers to likewise deliver the company's messages about the drug, and writers who engaged in the "ghostwriting" of medical and scientific articles in order to advance the Avandia agenda. "Ghostwriting" is a particularly insidious practice where a drug company authors a purportedly independent scientific paper and then pays someone else to place their name on the paper to give the appearance of independence and objectivity by suggesting that the independent person or group, and not the drug company, performed the research and authored the paper.

56. Defendant's Avandia message had two key components. First, Defendants propagated the message that Avandia was better at lowering blood sugar than other established drugs. That is, Avandia had superior efficacy. Defendants also represented that patients could stay on Avandia longer than the older drugs. Second, Defendants represented that, unlike the older diabetes drugs, Avandia had the additional benefit of actually lowering diabetics' cardiovascular risks. The notion that Avandia would actually lower diabetics' cardiovascular risk

was critical to Avandia's marketing. Defendants needed justification for the steep price difference between Avandia and the older established diabetes drugs. Defendants, however, knew or should have known that these representations were false, misleading, and likely to deceive. At best, Defendants had no data to support these claims. At worst, they were wholesale fabrications.

57. In today's health care market, physicians face extreme time constraints in determining which drugs and treatments are best. Physicians, along with formulary committees, purchasers, Pharmacy Benefit Managers ("PBMs") and policy makers rely upon a variety of trusted sources including independent studies for such information. However, often unbeknownst to the public, many of these sources are directly controlled or heavily influenced by pharmaceutical manufacturers such as Defendants. All of these sources contain susceptibilities that have been exploited by pharmaceutical manufacturers such as Defendants.

58. Among the tactics employed by Defendants were plans to create studies designed to illustrate Avandia's superior profile to both (a) placebo and (b) comparable medications designed to control Type II diabetes mellitus while providing funding to engage "key opinion" and "thought" leaders in publication worthy trials.

59. Upon information and belief, this scheme was carried out by: making false statements to consumers, Third-party Payors, physicians and pharmacies concerning the efficacy and safety of Avandia; training Defendants' employees in methods to conceal negative information regarding Avandia to avoid detection of their activities by Plaintiff and the Class, and instructing Defendants' employees to conceal negative information regarding Avandia to avoid detection of their activities by Plaintiff and the Class.

Incentives to Develop Deceptive Medical Literature

60. Upon information and belief, Defendants sought out, and provided incentives and funding to, doctors and researchers to develop deceptive and misleading medical literature for use in marketing.

61. A June 5, 2007 *The Bulletin* article reveals that Dr. Anne E. Peters, a diabetes expert who runs a clinic for Los Angeles County and who is affiliated with the University of Southern California medical school had previously received money from Defendants as a speaker on behalf of Avandia. Dr. Peters resigned from that position when she enumerated her concerns about Avandia's risks. Dr. Peters said that five years ago, she removed Avandia from the formulary (the list of preferred drugs) maintained by the Los Angeles Clinic. That meant that patients would receive Actos instead of Avandia. "The Avandia people, it was just so surprising, they asked me what I wanted to keep Avandia on the formulary." "Dr. Peters said that she asked the company to establish a database at the clinic that would track the outcomes of patients on both drugs. When she asked for the database, which would have cost several thousand dollars, she said a company representative replied: 'That's all you want? Other doctors ask to go to the Caribbean.'" Dr. Peters said, "They wanted to do everything but approve my request."

62. Despite being on notice of the potential for deadly heart attacks and heart related diseases, Defendants each opted for the bare minima of well-tailored clinical trials, of limited duration, such that little to no side effects were likely to be revealed. Thus, instead of conducting true scientific research in good faith to legitimately test the efficacy and safety of Avandia, Defendants focused on creating narrowly tailored studies specifically designed to enhance commercial value.

Physician Intimidation of Dr. Buse

63. A June 7, 2007 *Washington Post* article discusses Dr. Buse, who told a congressional hearing that in 1999, officials at SmithKline Beecham (a former pharmaceutical company that merged with GlaxoWellcome in 2000 to form GlaxoSmithKline PLC) began pressuring Dr. Buse after he questioned whether Avandia caused heart problems. In or around 1999, Dr. Buse was a presenter at a continuing medical education symposium sponsored by Eli Lilly and Company at which Dr. Buse was asked to discuss new therapies in diabetes. At the symposium, Dr. Buse presented slides stating that Avandia increased the risk of heart-related activities by 50 percent.

64. Thereafter in 1999, Dr. Buse wrote a letter to Tadataka Yamada, MD, the Chairman of Research and Development of Pharmaceuticals at SmithKline Beecham. In the 1999 letter, as the Associate Professor of Medicine and Director of the University of North Carolina Diabetes Care Center, Dr. Buse wrote that he reviewed every paper published and available on diabetic class medications on humans, and identified that Avandia has the potential to increase heart attacks and heart-related diseases, where the increase in heart-related deaths are the "relevant endpoints to be examined in the clinical trial program if one were to look for those kinds of changes in endothelial function." "I strongly believe that the rosiglitazone data set supports this kind of clinical decision making. I believe that caution is required until additional data are available."

65. Shortly after Avandia' s FDA approval, Defendants took action against Dr. Buse. In a June 1999 e-mail mail, Dr. Tachi Yamada, Defendant's head of research at the time, wrote to colleagues at the company:

> I plan to speak to Fred Sparling, [Dr. Buse's] former [department] chairman[,] as soon as possible. I think there are two courses of action.

> One is to sue [Dr. Buse] for knowingly defaming our product ... the other is to launch a well planned offensive on behalf of Avandia ....

Additionally, Defendants prepared and sent a letter to Dr. Buse, to be signed by him, "retracting" his statements about Avandia's increased cardiovascular risk.

66. In Dr. Buse's June 6, 2007 published statement to the U.S. House of Representatives Committee on Oversight and Government Reform, Dr. Buse recounts that after writing the 1999 letter to Defendants, Defendants called Dr. Buse numerous times emphasizing that there were some in the company who believed that Dr. Buse's actions were scurrilous enough to attempt to hold Dr. Buse liable for a $4 billion loss in market capitalization.

67. As promised, Dr. Yamada called Dr. Sparling at the University of North Carolina. Shortly thereafter and in response to GSK's pressure, Dr. Buse wrote to Dr. Yamada, "clarifying" his position on Avandia. In his letter, Dr. Buse stated that he continued to "believe as a clinical scientist that the null hypothesis should be that [Avandia] has the potential to increase cardiovascular events." Despite this belief, Dr. Buse stated that he had learned of "implied threats of lawsuits from my chairman [Dr. Sparling] and James Huang," who was then a product manager with a GSK, and, succumbing to the threat of legal action, Dr. Buse asked GSK to "call off the dogs." Under pressure, he signed the so-called " retraction letter," which had been authored for his signature by GSK officials.

68. The concealment of Dr. Buse's assessment regarding the dangers of Avandia was encouraged by Defendants, and Defendants continued to overplay favorably misleading articles regarding Avandia's side effects.

69. On March 15, 2000, Dr. Buse followed up his apprehension towards Avandia use by writing Dr. Jane Henney, the Commissioner at the FDA, regarding his concern "about the safety of rosiglitazone in light of its consistent negative impact on lipids documented in the FDA

registration data as well as a worrisome trend in cardiovascular deaths and severe adverse events in the subjects exposed to rosiglitazone versus active comparators."

70. In the 2000 letter to the FDA, Dr. Buse suggested that the FDA act forcefully to prevent the rampant abuse of clinical trial data by Defendants. Dr. Buse had knowledge that:

a. Defendants overstated the safety of the drug with respect to heart attacks and heart-related diseases, and that Defendants claimed that Avandia had been uniquely studied on patients with preexisting heart disease, but in fact these patients were excluded in clinical trials as Dr. Buse was the principle investigator in one of their trials;

b. Defendants show misleading materials for professional education touting the lipid lowering effects of Avandia when the data are from a small subset of patients with triglycerides over 400 mg/dl. "The overwhelming preponderance of data suggests that at high doses the drug is most likely to increase triglycerides than lower them;" and

c. Defendants' representatives "detailed" primary care doctors on the safety and efficacy of the antidiabetic medications to suggest that Avandia's "safety and clinical efficacy is greater when there is no comparative data available."

71. In Dr. Buse's letter to the FDA, he states that "there is something pervasive and systematic that I detect in my travels regarding the marketing of rosiglitazone [Avandia]. I have to admit that now when I give CME [continuing medical education] lectures, I spend about half my time discussing these issues. It seems to me that blatant selective manipulation of data has obfuscated relatively straightforward conclusions evident from the FDA data sets."

72. Defendants knew that the dissemination of information about Avandia's true cardiovascular risks would devastate its efforts to promote the drug. When doctors like Dr. Buse raised suspicion about Avandia's safety, Defendants set out to intimidate and silence them. Such was the official finding of the United States Senate's Finance Committee, which concluded in January, 2010 that Defendants had executed "an orchestrated plan to stifle the opinion" of Dr.

Buse, and that the intimidation scheme involved "executives at the highest level of Defendants, including then and current CEO Jean-Pierre Gamier."

Dr. Nissen's May 2007 NEJM Article Jolts Defendant's Fraud into High Gear

73. In a December 2007 floor speech, Senator Grassley revealed that Dr. Steve Haffner, a professor of medicine at the University of Texas Health Sciences Center, San Antonio, and a consultant for Defendants, leaked to Defendants the draft of a study critical of Avandia that was to appear in the New England Journal of Medicine (NEJM). Dr. Haffner was entrusted with a confidential copy of the manuscript draft because he was peer-reviewing the study for the NEJM.

74. The study's lead author, Dr. Steven Nissen, professor of cardiology at the Cleveland Clinic, found that Avandia was associated with a 43-percent increased risk of heart attacks, one of the main health outcomes physicians hoped to avoid by treating diabetic patients with medication. According to documents produced by Defendants, the leaked manuscript was widely disseminated within the Company, and allowed Defendants to launch a public relations plan to protect Avandia, a multi-billion dollar product.

75. The Committee staff reviewed documents showing that over 40 executives at Defendants' received and/or learned of the results in the leaked study, including then CEO Dr. Jean-Pierre Garnier; head of research, Dr. Moncef Slaoui; Vice President of Corporate Media Relations, Nancy Pekarek; and Defendants' Senior Advisor, Sir Colin Dollery.

76. Before Dr. Nissen's study on Avandia was published, Defendant's statistical experts were examining the study for potential flaws. In addition, Defendants officials were drafting ''key messages'' to undermine the main conclusion of the Nissen study. Defendants had already published several large trials on Avandia (rosiglitazone) including studies named

ADOPT and DREAM. After Nissen's study was published, Defendants began publicly referencing those trials, as well as another trial called RECORD, in what appeared to be an effort to further repudiate any link between Avandia and heart attacks.

77. RECORD is a study Defendants had been conducting for several years. Defendants later published the interim results of the RECORD trial in what appeared to be an attempt to cast doubt on Nissen's results. However, according to the Senate Finance Committee, internal Defendant's emails indicate that Defendant's executives, not the study's independent steering committee, made the final decision to publish the RECORD trial results. Further, according to the Committee, based on a review of emails, it can be argued that the authors of the RECORD trial appeared more concerned about countering claims that Avandia may be associated with heart attacks, than in trying to understand the underlying science. While circulating a draft of a manuscript on the RECORD trial, one of the authors wrote to his colleagues, ''[W]hat's to stop [Nissen] adding the events from RECORD to his meta-analysis and re-enforcing his view?''

78. Further, after the authors of the RECORD study submitted their paper to the NEJM, one of the peer reviewers and several of the NEJM editors replied, ''an explanation for the continued use of [Avandia] is needed in this manuscript.''

79. Committee investigators also learned that Defendants were aware since at least 2004 that the RECORD trial was statistically inadequate, or ''underpowered'' to answer questions regarding cardiovascular safety. Such ''inconclusive'' results could be favorable to Defendants and the marketing strategy for Avandia. Further, experts were advising Defendants since 2004 about the possible biological mechanisms related to why Avandia may cause an increased risk for heart attacks.

80. However, Defendants appeared eager to design studies to prove that Avandia was safer than its competitor ACTOS (pioglitazone), which is manufactured by Takeda.

81. At a July 30, 2007, safety panel on Avandia, Food and Drug Administration (FDA) scientists presented an analysis estimating that Avandia use was associated with approximately 83,000 excess heart attacks since the drug came on the market. Had Defendants considered Avandia's potential increased cardiovascular risk more seriously when the issue was first raised in 1999 by Dr. Buse, as well as by some of their own consultants in later years, some of these heart attacks may have been avoided.

Response to the Nissen Study

82. In March 2007, Defendants held a meeting with company officials and academic advisors to discuss several studies on Avandia and its cardiac risks and benefits. Several presentations were made about studies on Avandia's possible cardiac risk. During the discussion of a Defendants' meta-analysis (integrated study) and a study Defendants commissioned by Ingenix, Defendants noted that the academic advisors stated the following:

> Dr. NAME REDACTED commented that the [cardiovascular] effect seen in the Integrated Clinical Trials Analyses with rosiglitazone was small but real, and that it is counter to the proposed [cardiovascular] benefits associated with Avandia. Dr. NAME REDACTED agreed, noted that all data point to rosiglitazone having a hazard ratio greater than unity. . . . Dr. NAME REDACTED summarized the discussion on the Integrated Clinical Trials data by stating that rosiglitazone causes weight gain and edema, leading to a greater number of events.

Moreover, during the discussion of the DREAM trial, a cardiologist from Stanford stated:

> [T]he diabetes prevention afforded by rosiglitazone was very impressive, but there was no cardioprotective benefit. He then asked what the point of diabetes prevention is if there is no cardiovascular benefit. [Emphasis added]

When discussing ADOPT, the academic advisors concluded that, ''The data in ADOPT and DREAM as well as in the CV Clinical Trials are consistent in indicating a signal for heart failure and ischemic events.'' According to Defendants interal documents, Defendant's experts were discussing problems with DREAM as early as 2006.

83. Around this same time, Dr. Steven Nissen began studying the potential cardiac risks of Avandia, by reviewing data found in previously published studies. He placed several requests to Defendants asking for patient level data on several studies published about Avandia. However, Defendants would provide the requested data only if Dr. Nissen agreed to use one of Defendants statisticians for the analysis. Dr. Nissen refused to use the Company's statistician, citing a need to maintain independence.

84. On May 2, 2007, Dr. Nissen submitted an analysis of 42 published and unpublished clinical trials on Avandia to the NEJM for peer review and publication. NEJM then sent confidential copies of the study to several independent experts, including Dr. Steve Haffner, to peer review the Nissen study. According to NEJM, peer reviewers must acknowledge in writing that the material they are reviewing is confidential, not to be shared with others, and is to be destroyed or returned to the medical journal after a review is completed.

85. However, the very next day, May 3, 2007, Dr. Haffner faxed Dr. Nissen's unpublished study to a GSK executive. Dr. Haffner wrote ''confidential'' on the fax cover sheet and checked a box marked ''urgent.''

Leaked Manuscript and a Massive Defensive Campaign

86. One day after receiving the unpublished study from Dr. Haffner, Defendants produced a detailed, 8-page analysis of Dr. Nissen's paper, weeks before the paper's public release. The Defendant's statistician attempted to find deficiencies in Nissen's meta-analysis but

noted, ''The selection of trials therefore appears to be thorough, though others more familiar with the trials can comment more knowledgeably.''

87. The Defendants' statistician also performed a regression analysis on each study that Dr. Nissen used in his meta-analysis to see if the effects of myocardial infarction and/or cardiovascular death would still appear. The statistician stated, ''These results are very similar to the conclusion from the [Nissen] paper using the Peto method. As such there is no statistical reason for disregarding the findings as presented.''

88. The Defendant's statistical analysis was circulated to senior executives within the company. These executives then discussed several large trials, such as RECORD, DREAM and ADOPT that Defendants could use to combat Dr. Nissen's analysis. RECORD was an ongoing trial that had not been published. On the other hand, DREAM and ADOPT were published and were included in Dr. Nissen's analysis. Defendants, as well as the FDA, had also performed their own meta-analyses.

89. Both meta-analyses were consistent with Dr. Nissen's results. On May 8, 2007, Dr. Moncef Slaoui, head of research at GSK, wrote an email to several company executives. Commenting on the meta-analyses, he wrote:

> —FDA, Nissen and GSK all come to comparable conclusions regarding increased risk for ischemic events, ranging from 30 percent to 43 percent!
> —FDA and Nissen (but no final data from GSK [to] date) reach the conclusion of an [hazard ratio] for death (CHF + IHD) of 1.72 or 1.75!

90. Dr. Slaoui also noted in this email that a GSK commissioned study by Ingenix did not find any significant problems with rosiglitazone. Ingenix had performed an epidemiological study of Avandia. While medical experts place greater importance on a clinical trial over an epidemiological study, Dr. Slaoui sought to highlight the Ingenix results. He also expressed concern that a beneficial effect was observed (6 to 16 percent) in the PROactive study of ACTOS

in high-risk cardiovascular disease patients. Dr. Slaoui asked, ''How can we reinforce the value of the [Ingenix] study? The FDA criticizes the fact that we excluded cases of sudden cardiac death.'' He then asked his team to strategize further on the issue:

> [W]hat studies could we offer the FDA to further assess the contradictory data between the integrated study and the two others? can we expand Record? Propose something else (very high risk patients? ok? ethical?), compare to Actos for superiority on some end points?

91. By May 9, 2007, GSK began drafting ''key messages'' to counteract the findings of the Nissen study. In an email, Defendant's Vice President for Corporate Media Relations noted, ''The Nissen analysis is one way of looking at the data, but it doesn't reflect all we know about the safety of this medicine. . . . [W]e are not seeing a proven link between Avandia and increased cardiovascular deaths. . . .''

92. On May 9, 2007, Sir Colin Dollery, a senior consultant to Defendants, laid out many of the problems with Avandia in an email to Dr. Slaoui and others. He wrote:

> To a great extent, the numbers are the numbers, the [Nissen] analysis is very similar to our own. . . . We cannot undermine the numbers but I think they can be explained so we must concentrate on effective risk management.

Later in the email, Sir Dollery noted that the PROactive study on ACTOS (pioglitazone) is undermining Avandia (rosiglitazone). He wrote:

> The main argument here lies in that pioglitazone [ACTOS] causes a small reduction of LDL [Low-Density Lipoprotein] and rosiglitazone causes a small elevation. . . . [W]e should search for evidence that the use of statins in diabetics generally and with rosiglitazone in particular has risen steeply over the time the thiazolidenediones have been on the market. We can then argue that any problem that existed with LDL is now controlled or controllable. It would also be worth obtaining the evidence that the use of antihypertensives in diabetics has also been increasing rapidly.

93. On fluid retention and links with cardiovascular disease, Sir Dollery mentioned a possible mechanism to explain how Avandia may cause heart attacks. He wrote:

> If [fluid retention is] substantial in patients with an impaired myocardium it can lead to [cardiac heart failure] and to cardiac ischemia by decreasing myocardial efficiency in the face of existing coronary disease. . . . If there is criticism of GSK it might be that we were a bit slow offthe [mark] in making firm recommendations about the use of diurectics . . . and recognizing that the sodium retention is mediated via distal renal tubular ENaC.

94. On May 21, 2007, NEJM published online Dr. Nissen's metaanalysis that found a link between Avandia and heart attacks. That same day, Defendants responded, "GSK strongly disagrees with the conclusions reached in the NEJM article, which are based on incomplete evidence and a methodology that the author admits has significant limitations." Instead, Defendants highlighted the results of company sponsored trials like RECORD as "the most scientifically rigorous way to examine the safety and benefits of a medicine."

95. In a subsequent letter to The Lancet, GSK maintained that the RECORD trial is "compelling evidence" for the safety of Avandia. On May 23, 2007, a GSK official emailed members of the RECORD steering committee, the group of independent academics overseeing the study, to alert them of a teleconference to be held the following day. GSK officials also emailed internal talking points to help guide their discussion with the steering committee. However, it appears that prior to receiving input from the steering committee, Defendants had already decided to publish the RECORD results. Later that same day, a GSK official wrote, ". . . we've decided to disclose the results. . . ."

96. The following day, GSK officials discussed potential problems if the academics on the RECORD steering committee raised concerns about publishing the interim results of the RECORD trial. In an email, one GSK official wrote:

> [I]f the Steering Committee [SC] are reluctant to publish— Frank and I will argue the case that there is a balance to be drawn between very negative press coverage and specific reassurance for the patients in the study. However if the SC believe that publishing interim data will fatally

> damage their ability to bring the study to a completion— Frank and I will bring that opinion with reasons back to GSK, before pursuing the line— that a decision has been made—live with it.

97. A few hours after this email, the acting chair of the RECORD steering committee, contacted the NEJM to inquire about publishing the interim results. The editor of the NEJM responded that the journal would be interested in publishing the study.

98. By May 29, 2007, several authors of the RECORD study began passing around a manuscript, discussing the results, and offering suggestions for improvement. The third author on the RECORD study wrote, "We do not find more myocardial infarctions with rosiglitazone treatment, but again there is a tendency supporting the Nissen argument. It is important to stress that it does not affect cardiovascular death." That same day, a senior author of the RECORD study, wrote:

> There are several striking issues:
>
> > (1) The HR ratio (and 95 percent CI) for MI in RECORD is not inconsistent with Nissen's—and he had more events; what's to stop him adding the events from RECORD to his meta-analysis and re-enforcing his view? . . .
> > (2) Same is for CV death, although the number of events in RECORD and in the meta-analysis are similar and at least in RECORD the HR is in the other direction!
> > (3) Manuscript looks to downplay the 239 percent INCREASE in HF. I have taken the liberty of doing some rewording.

99. Once a study is submitted to a journal, the journal editors then send the article to several experts for peer-review. After the review, the editors send the peer-review comments back to the author. On June 1, 2007, the RECORD authors received a reply from NEJM regarding their earlier submitted manuscript. The NEJM editors summarized the issues presented by all 8 peer reviewers, many of whom were highly critical of the study in their reply.

100. Reviewer A, along with other reviewers, asked that the authors "modify the language in multiple locations in the manuscript to tone down your conclusions." The editor also noted, "[I]n the opinion of all the readers, the data that you present are completely compatible with the results of the meta-analysis by Nissen and the meta-analysis for myocardial ischemic events posted on the GSK Web site."

101. Regarding the comments of Reviewer B, the editors wrote that for myocardial infarction the "estimates in the RECORD trial and the Nissen meta-analysis" overlap in their confidence intervals, meaning that they found a similar trend for heart attacks. They continued, "The editors feel strongly that your data do not support the statement that the RECORD results for MI contradict the Nissen meta-analysis; this statement must be removed or modified."

102. Reviewer C noted that the RECORD trial is not blinded, and pointed out "the serious problem of the low event rate, especially for MI events, in this study." He continued to ask, "Do you have an explanation for the very low event rate?" This reviewer also noted the "need to greatly tone down your language to reflect the substantial level of uncertainty in the data."

103. Reviewer D questioned the need for keeping rosiglitazone on the market. "The editors also agree that an explanation for the continued use of rosiglitazone is needed in this manuscript."

104. The NEJM published the interim analysis of the RECORD study on July 5, 2007. The GSK study authors concluded that the data was "insufficient" to find a link between Avandia and heart attacks.

105. However, an editorial by the NEJM questioned the RECORD study, as well as several of Defendants' studies of Avandia such as DREAM and ADOPT. The authors of the

editorial wrote, ''The DREAM trial and ADOPT focused largely on marketing questions and failed to address questions of myocardial infarction-related risk or benefit directly.'' In addition, the editorial noted that the RECORD trial had ''several weaknesses in design and conduct'' including a lack of blinding when treatment was assigned. The authors also pointed out that events of myocardial infarction would have been a preferred clinical endpoint for the study. Studies are normally designed to evaluate certain clinical endpoints or disease symptoms such as heart attack, tumor size, or depression. The authors also added that the RECORD study was not powered (or designed) to detect a myocardial infarction as an endpoint.

106. On June 6, 2007, the House of Representatives Committee on Oversight and Government Reform held a hearing on Avandia. Despite mounting criticism of the RECORD trial, Dr. Slaoui again highlighted the study in his sworn testimony. ''I will say that we found the RECORD data which we published yesterday in the New England Journal of Medicine very reassuring, recognizing that it is interim and therefore not fully conclusive.''

107. That same day, Defendants dismissed the idea that Dr. Nissen's study spurred the publication of the RECORD interim results. Instead, the Company placed blame on the media. In talking points created for its sales force, GSK stated, ''Because of the widespread media coverage of the NEJM [Nissen] meta-analysis and the confusion it has created, the RECORD Steering Committee decided it was important to publish the interim analysis in the interests of patient safety.''

108. Regarding its competitor Takeda, which sells ACTOS, Defendants advised its sales force if asked questions about the PROactive study:

> Please do not discuss Actos or the Proactive study with your physicians. For questions regarding Actos or the Proactive study, healthcare providers should contact Takeda. GSK's focus is on Avandia. Communicate the key points from the interim analysis of RECORD to your physicians.

The Record Trial as a Marketing Tool for Competition

109. Despite attempts to highlight the RECORD study, it appears that Defendants knew for years that the study was ''underpowered,'' i.e., the study did not provide sufficient data to test for cardiovascular safety; and executives appeared more concerned about designing a study to limit competition from ACTOS. Such evidence can be found in a GSK slide presentation, emails, and other documents created in 2004 to 2006.

110. For instance, in an undated slide show, apparently created in 2004, Defendants noted that RECORD does not have sufficient ''power.'' The slide presentation also noted that GSK was trying to create studies to counter the PROactive study on ACTOS that Takeda planned to release.

Slide number 6 titled, ''PROactive: Potential Impact,'' noted that Defendant's challenge was to ''maintain share in growing market over next 2–3 years.''

Slide number 8 reads:

> Situation Summary:
> • We have a gap
> —In 2005 Actos will have some [cardiovascular] outcome data
> • To keep our share of the growing class
> —Additive benefit to RECORD of non-inferiority result
> • However this gap may be permanent
> —RECORD has a lower event rate than expected
> PROPOSAL
> Fill this gap with an outcome study reporting in 2007

Slide number 10 compared the potential impact of a new GSK study to counter the marketing danger of PROactive and the potential impact on sales in UK pounds in 2010. The slide reads: ''Timely CV Outcomes data would more than fill the RECORD 'potential gap' and would have twice the impact on our sales than PROVerDate active.'' The final slide pointed out

that GSK should do a ''kick off study only after review of results from Proactive in Sept 2005 and assessing benefits/risks.''

111. A second instance is found in a June 2005 email where GSK executives discussed the need for a study to counter PROactive. In the email, a GSK official wrote, ''Clearly no patients will be recruited until [we] have made a decision based on the go-no go criteria from the PROactive data. However, there is a great deal of EU commercial push to initiate this study in 2005.''

112. A third case is found in an internal GSK document outlining an upcoming meeting for December 2004. Several points were discussed about RECORD and PROactive. Regarding RECORD, the document noted that RECORD has ''low events rates.'' This means that the study did not have the statistical ''power'' to give sufficient cardiovascular event data. The document also stated, ''PROactive results to be coming soon—need to be able to respond to a variety of different outcomes. Communications plan in place for various possible outcomes of PROactive.''

113. A fourth instance is found in a briefing document for a June 2005 meeting on Avandia's cardiovascular plan. The document notes several ''important limitations of RECORD.''

> —the study will not be available until 2009
> —the current observed rate for the primary endpoint is very much lower (approximately 3.5 percent per annum) than that anticipated in the original protocol (11 percent per annum).

114. A fifth case is found in another of Defendants' emails. On July 26, 2005, Defendants' officials began emailing each other about potential problems with RECORD and how the PROactive study by Takeda on ACTOS will create problems for Avandia. One official wrote:

> Ron Krall [then GSK Chief Medical Officer] has asked Lawson [unknown GSK executive] to provide an urgent update to David Stout [then GSK President of Global Pharmaceutical Operations] regarding RECORD. In particular he has asked for our ''intent to manage information flow in Europe to manage the competitive situation.'' Clearly we can provide a summary of the communications around PROactive but I wonder if you could put a few sentences together regarding the communications piece around RECORD.

115. A sixth incident is documented in July 2005, when Defendants' officials continued expressing concerns about cardiovascular problems with Avandia and potential problems arising from the PROactive study which focused on positive findings with ACTOS. Defendants held a meeting on July 18, 2005 to discuss the need for a study to compete with PROactive. The briefing document from this meeting discussed the ''European Commercial Need'' for a study:

> A recently completed evidence gap analysis completed by the Metabolic Centre of Excellence has identified the need for the rapid generation of clinical endpoint data to support the superiority of rosiglitazone [Avandia] for the prevention of future cardiovascular clinical events in patients with [type 2 diabetes mellitus]. Publication of the PROactive data may result in important commercial disadvantage in Europe. We therefore have the opportunity to start a CV outcomes study with the aim of getting superiority data in 2007.

116. The document also noted that Defendant's studies provided insufficient data on cardiovascular outcomes:

> The primary endpoint in RECORD is powered for noninferiority and taking into account the low observed event rate, it is unlikely that this study will demonstrate any potential for [Avandia] combination to be superior in terms of the primary endpoint compared to SU+MET combination therapy. DREAM and ADOPT are collecting CV safety data, but these are low risk populations and it is unlikely that [Avandia] will be superior to controls for the prevention of CV events.

117. In a May 21, 2007 FDA press release, the FDA announced that safety data from controlled clinical trials have shown that there is a potentially significant increase in the risk of heart attack and heart-related disease in patients taking Avandia. The FDA press release also mentioned an interim analysis of data from the RECORD trial and unpublished re-analyses of data from DREAM, which provide contradictory evidence about the risks in patients treated with Avandia.

118. However, the May 21, 2007 FDA press release also mentions that Defendants provided the FDA with a pooled analysis (meta analysis) of 42 randomized, controlled clinical trials in which Avandia was compared to either placebo or other antidiabetic therapies in patients with Type II diabetes. The pooled analysis revealed that patients receiving short-term (most studies were 6-months duration) treatment with Avandia may have a 30-40 percent greater risk of heart attack and other heart-related disease than patients treated with placebo or other antidiabetic therapy. "This would be a significant concern since patients with diabetes are already at an increased risk of heart disease." Patients suffering from Type II diabetes have a 20.2 percent risk of experiencing a heart attack within seven years.

119. The May 21, 2007 publication of the New England Journal of Medicine's article *Effect of Rosiglitazone on the Risk of Myocardial Infarction and Death from Cardiovascular Causes*, which was written by Cleveland Clinic cardiologists Dr. Nissen and Dr. Wolski, called Avandia's safety into question. This published journal article links Avandia to a potential increase in the risk of heart attacks compared to other diabetic drugs or a placebo. The meta-analysis was based on a review of more than 40 existing clinical studies involving nearly 28,000 patients. Defendants' own meta-analysis also found indications of increased risk, but Defendants concluded that the number of adverse events was low, and therefore drew no negative conclusion

from that data analysis. Thus, Defendants deliberately concealed critical information regarding the serious health risks associated with Avandia.

120. In a May 31, 2007 *Washington Post* article, Dr. Nissen criticized Defendants' study stating that the company's study referred to such small subsets of data, so that Defendants could not draw a negative conclusion. "Somebody went back and looked for something that would support their contention. This is not a scientifically proper way to analyze data."

121. On May 23, 2007, the FDA disclosed that it asked Defendants to add a more prominent "black box" label warning to address the risks of a different side effect, heart failure, on all Avandia products. Heart failure is a chronic condition in which the heart has trouble pumping blood, as opposed to a heart attack, where blood is prevented from flowing from the heart and immediate death can result. The labels on Avandia already warned patients about heart failure, though not with black box labels.

122. On May 29, 2007, the FDA held a Stakeholder Meeting to discuss the recent safety alert for Avandia. The meeting was composed of invited patients, health care professionals, and government agencies and the FDA's goal was to ensure that "the nuanced message" about Avandia was both clearly articulated and reached the correct audience.

123. A June 5, 2007 *Houston Chronicle* article states that Defendants released the results of a study that compares Avandia and two other diabetes drugs in nearly 4,500 people around the world. The first few years of a six-year study shows similar rates of heart-related deaths and hospitalizations among those on Avandia versus those on the other drugs. Some doctors said the results showed slightly more heart problems with Avandia – a bad sign even if the difference was so small that it could have occurred by chance alone. "This study, which was designed to show the benefit of rosiglitazone (Avandia), if anything shows the opposite," said

Dr. David Nathan, chief of diabetes care at Massachusetts General Hospital. Dr. Nathan had no role in the study or financial ties to any diabetes drug makers.

124. Further, Avandia's pre-marketing clinical trials were specifically designed to produce similar rates of heart-related adverse events and do not support the assertion that the medication is less likely to cause dangerous heart-related conditions. Manufacturers, including Defendants, fund clinical trials, where the manufacturers create and control the research design. In a 2001 study published in the *New England Journal of Medicine*, researchers found that more than two-thirds of the academic institutions accepted research contracts that prohibit researchers from changing the research design of sponsors, including Defendants. Half of the medical centers allowed commercial sponsors to "draft manuscripts reporting the research results, with the investigators' role limited to review and suggestions for revision."

125. In a 2001 issue of the *New England Journal of Medicine*, thirteen editors of the world's most prestigious medical journals issued an alarming joint statement highlighting the extent and consequences of the commercial takeover of clinical research. In the report they state:

> Until recently, academic, independent clinical investigators were key players in design, patient recruitment, and data interpretation in clinical trials. The intellectual and working home of these investigators, the academic medical center, has been at the hub of this enterprise, and many institutions have developed complex infrastructures devoted to the design and conduct of clinical trials. But, as economic pressures mount, this may be a thing of the past. Investigators may have little or no input into trial design, no access to the raw data, and limited participation in data interpretation. These terms are draconian for self-respecting scientists, but many have accepted them because they know that if they do not, the sponsor will find someone else who will.

126. FDA regulations and industry standards prohibit Defendants from misrepresenting scientific evidence that supports (or fails to support) claims that their respective drug is safe and

effective for a specific condition. Thus, anecdotal evidence of a drug's usefulness for a given condition could not be presented as the equivalent of the findings of a well-designed clinical trial. Failure to comply with these standards violates Defendants' legal duty to provide accurate and non-misleading information.

127. Nevertheless, despite conclusive and reliable studies that conclude Avandia's adverse effect of increased heart attack, heart failure, and heart-related disease, and the FDA's stringent regulations and recommendations to Defendants regarding the black box warning of Avandia's adverse side effects, Defendants continued and continue to mislead and deceive consumers by placing full page advertisements in newspapers nationwide declaring that Defendants have "conducted an unprecedented number of clinical trials in order to continuously evaluate the safety of *Avandia*, including its impact on the cardiovascular system. The response to this commitment from well-informed experts and researchers has been encouraging."

128. Defendants deceive consumers and members of the medical community by overemphasizing controlled and misleading favorable studies, while failing to disclose studies illustrating Avandia's dangerous side effects. Defendants have and continue to expose vulnerable patients with Type II diabetes, including Plaintiff and Class members, to an increased risk of heart attack and heart-related diseases.

129. Defendants have unfairly and unjustly profited from their failure to adequately inform physicians, consumers, and the medical and healthcare community that Avandia could cause profound and long-term injury and, in some cases, death. Sale of Avandia without adequate warning, and based upon false representations regarding its safety and efficacy, violates the Pennsylvania Unfair Trade Practices and Consumer Protection Law.

V. Fraudulent Concealment of Defendants' Conduct

130. The applicable statute of limitations regarding the claims of Plaintiff and the Class has been tolled by Defendants' fraudulent concealment of their unlawful, conspiratorial deceit, as alleged in detail throughout this Complaint.

131. As evidenced by the allegations in this Complaint, Defendants have employed and continue to employ practices and techniques of secrecy in order to avoid detection of, and to fraudulently conceal, their deceptive and conspiratorial behavior regarding the safety and efficacy of Avandia and Avandia's risks associated with heart attacks and heart-related diseases.

132. Despite taking on the responsibility to reveal this information to the general public, Defendants have kept such information hidden.

133. As such, Plaintiff and the Class were not effectively alerted to the existence and scope of this industry-wide fraud and were not on notice of their potential claims until shortly prior to the filing of this Complaint.

134. Plaintiff and the Class could not have acquired such knowledge through the exercise of reasonable diligence.

135. Through their public statements, marketing and advertising, Defendants' self-concealing scheme and affirmative conduct to perpetuate their fraud deprived Plaintiff and the Class members of actual or presumptive knowledge of facts sufficient to put them on notice as to their potential claims.

VI. Injury to Plaintiff and the Class

136. Defendants' deceptive and misleading marketing scheme increased the number of prescriptions of Avandia written and filled during the Class Period. Because Defendants withheld material information about the true safety and efficacy of Avandia, the prescribing

physicians did not have the knowledge necessary to make informed decisions regarding Avandia prescriptions. Plaintiff and the Class, unaware of Defendants' scheme, paid for these prescriptions. Although more effective, safer, and less expensive alternatives are available, Defendants' promotion and marketing of Avandia's safety and effectiveness has been highly successful, resulting in Defendants receiving billions of dollars in profits, representing ill-gotten gains to which Defendants were not entitled.

137. Plaintiff and similarly-situated Class members bear the ultimate responsibility of paying for their Avandia prescriptions.

138. PBMs prepare a "formulary," which is a list of the drugs that are approved for coverage by their third-party payor clients, such as Plaintiff and Class members. In order for a drug to be listed on the formulary, it must be assessed by the PBM for clinical safety, efficacy, and cost effectiveness. Further, where a PBM finds that a drug has an advantage over competing drugs, that drug is given a preferred status on its formulary.

139. The level of preference on the formulary corresponds with the amount that a plan participant must contribute as a co-payment when purchasing a drug – the higher the preference, the lower the co-payment, the more likely that the drug will be purchased by a prescription plan's beneficiary in lieu of a cheaper or more cost effective alternative, and *vice versa*. As such, the higher a drug's preference on the formulary, the more likely it is for a doctor to prescribe that drug. This system is well known to pharmaceutical manufacturers, including Defendants.

140. Due to the large number of drugs purchased through third-party payors, it is vital to a drug manufacturer's economic interests to have its product listed on as many formularies as possible.

141. By directly and falsely promoting Avandia as safe and effective for Type II diabetes and training their sales forces and representatives to avoid alerting the FDA to their activities and to dismiss any safety concerns raised by physicians, Defendants influenced PBMs to place Avandia high on formularies.

142. Defendants falsely promoted Avandia as safe and effective directly to PBMs in order to get Avandia placed on, or placed more favorably than its competitor drugs on the PBM formularies.

143. Therefore, Defendants' failure to adequately inform consumers, third-party payors and those in the medical community that the use of Avandia dangerously increases the risk of heart attacks and heart-related diseases, and their false and misleading promotion of Avandia's efficacy over competing less expensive antidiabetic drugs, causes patients and third-party payors to pay for Avandia, which is neither safer nor more effective than other less expensive antidiabetic drugs.

CLASS ACTION ALLEGATIONS

144. Plaintiff brings this suit as a Class action pursuant to Rule 23(b)(2) and (b)(3) of the Federal Rules of Civil Procedure, on behalf of a Class consisting of:

> All health insurance companies, third-party administrators, health maintenance organizations, self-funded health and welfare benefit plans, third-party payors and any other health benefit provider, in the United States of America and its territories, which paid or incurred costs for the drug Avandia, for purposes other than resale, since May 25, 1999. Excluded from the Class are employees of Defendants, including its officers or directors, and the Court to which this case is assigned.

145. The proposed Class is sufficiently numerous, as thousands of members of the Class were induced to pay for Avandia through Defendants' scheme. The Class members are so numerous and dispersed throughout the United States that joinder of all members is

impracticable. The Class is composed of thousands of third-party payors, and the disposition of their claims in a Class action will benefit both the parties and the Court. It is estimated that in 2007, at least half a million individuals nationwide received prescriptions for Avandia. Defendants sell millions of doses of Avandia in the United States every year, and thus the Class is sufficiently numerous to make joinder impracticable, if not outright impossible. The Class members can be identified by, *inter alia*, records maintained by Defendants, pharmacies, and PBMs.

146. Common questions of law and fact exist as to all members of the Class and predominate over any questions affecting solely individual members of the Class. Among the questions of law and fact common to the Class members are:

a. whether Defendants misrepresent the safety and efficacy of Avandia, to the financial detriment of the Class;

b. whether Defendants' acts and omissions violate, *inter alia*, the Pennsylvania Unfair Trade Practices and State Consumer Protection Laws;

c. whether Defendants make material misrepresentations of fact, or omit to state material facts regarding the severe heart attacks and heart-related diseases and risks associated with Avandia, which material misrepresentations or omissions operate as a fraud and deceit upon the Class;

d. Whether Plaintiff and the class paid more for Avandia than for other efficacious drugs that were available at a cheaper price;

e. whether persons who took Avandia are at increased risk of severe and permanent injuries, including liver damage and/or failure, cardiac damage and visual impairment and damage;

f. whether, in marketing and selling Avandia, Defendants failed to disclose the dangers and risks to the health of persons ingesting the drug;

g. whether Defendants failed to warn adequately of the adverse effects of Avandia;

h whether Defendants misrepresented in their advertisements, promotional materials and other materials, among other things, the safety, potential side effects and convenience of Avandia;

i. whether Defendants knew or should have known that the ingestion of Avandia leads to serious adverse health effects;

j. whether Defendants adequately tested Avandia prior to selling it;

k. whether Defendants manufactured, marketed, distributed and sold Avandia notwithstanding their knowledge of the drug's dangerous nature;

l. whether Defendants knowingly omitted, suppressed and/or concealed material facts about the unsafe and defective nature of Avandia from government regulators, the medical community and/or the consuming public;

m. whether the Class has been damaged, and if so, the extent of such damages and/or the nature of the equitable relief, statutory damages, or punitive damages to which the Class is entitled;

n. whether Defendants were and are unjustly enriched by its acts and omissions, at the expense of the Class;

o. the amount of attorneys' fees, prejudgment interest, and costs of the suit to which the Class is entitled.

147. Plaintiff's claims are typical of the claims of the members of the Class because Plaintiff and the Class sustained damages arising out of the Defendants' wrongful conduct as

detailed herein. Specifically, Plaintiff, having expended substantial sums for the purchase of Avandia, assert claims that are typical of the claims of the entire Class, and will fairly and adequately represent and protect the interest of the Class.

148. Plaintiff will fairly and adequately protect the interests of the Class members and has retained counsel competent and experienced in class action lawsuits.

149. Plaintiff has no interests antagonistic to or in conflict with those of the Class members and therefore should be adequate as representatives for the Class members.

150. A Class action is superior to other available methods for the fair and efficient adjudication of this controversy since joinder of all members of the Class is impracticable. Furthermore, because the damages suffered by individual members of the Class may in some instances be relatively small, the expense and burden of individual litigation make it impossible for such Class members individually to redress the wrongs done to them. Also, the adjudication of this controversy through a Class action will avoid the possibility of inconsistent and possibly conflicting adjudications of the claims asserted herein. There will be no difficulty in the management of this action as a Class action.

151. Plaintiff and the Class have suffered irreparable harm and damages, and continue to suffer losses, thereby allowing these violations of law to proceed without remedy, and allowing Defendants to retain the proceeds of their ill-gotten gains.

CAUSES OF ACTION

FIRST CAUSE OF ACTION

VIOLATIONS OF THE PENNSYLVANIA UNFAIR TRADE PRACTICES AND CONSUMER PROTECTION LAW ("UTPCPL"), 73 Pa.C.S.A. § 201-1 ET SEQ.

152. Plaintiff incorporates by reference all preceding paragraphs as if fully set forth herein.

153. At all times material hereto, Defendants were a manufacturer, marketer, seller and/or distributor of Avandia within the meaning of the Pennsylvania Unfair Trade Practices and Consumer Protection Law ("UTPCPL"), 73 Pa.C.S.A. § 201-1 *et seq.*

154. At all times material hereto, the conduct described above and throughout this Complaint took place within the Commonwealth of Pennsylvania and constitutes unfair methods of competition or unfair or deceptive acts or practices in violation of § 201-2(4),(v),(vii) and (xxi) of UTPCPL, 73 Pa.C.S.A. § 201-1 *et seq.*

155. The UTPCPL applies to the claims of all the class members because the conduct which constitutes violations of the UTPCPL by Defendants occurred within the Commonwealth of Pennsylvania.

156. At all times relevant and material hereto, Defendants conducted trade and commerce within the meaning of the UTPCPL, 73 Pa.C.S.A. § 201-1 *et seq.*

157. Defendants' deceptive marketing scheme concerning Avandia violates the UTPCPL because, *inter alia*, Defendants:

a. knowingly conceal, suppress, or omit material information regarding Avandia's safety and effectiveness from Plaintiff and Class members and to their financial detriment, with the intent to induce reliance upon such concealment, suppression, or omission;

b. knowingly misrepresent the safety and efficacy of Avandia from Plaintiff and Class members and to their financial detriment, with the intent to induce reliance upon such misrepresentation; and

c. market, promote, and advertise Avandia as a safe and effective drug when the purported safety and efficacy is deceptive and unfounded.

158. Defendants' unlawful conduct as described herein arose, is directed, and emanates from Defendants' headquarters to the detriment of Plaintiff and Class members.

159. Defendants' concealment, suppression, omissions, misrepresentations, deceptions, and unconscionable and fraudulent practices has the tendency, capacity, and likelihood to deceive Plaintiff and the Class members.

160. Defendants intend, or consciously disregard, that Plaintiff and the Class members rely on its concealment, suppression, omissions, misrepresentations, deceptions, and unconscionable and fraudulent practices, so that they are able to purchase Avandia.

161. Defendants' concealment, suppression, omissions, misrepresentations, deceptions, and unconscionable and fraudulent practices cause Plaintiff and the Class members to suffer ascertainable losses in the amount of the monies they overpay for Avandia, and/or pay for more Avandia prescriptions, without knowing the drugs' efficacy or lack thereof for which they are marketed, promoted, or advertised.

162. Defendants deceived and continue to deceive consumers. This conduct constitutes unfair or deceptive acts or practices within the meaning of the UTPCPL. This illegal conduct is continuing, with no indication that Defendants will cease.

163. Defendants' actions in connection with the advertising, marketing, selling and distribution of Avandia as set forth herein evidences a lack of good faith, honesty and observance of fair dealings so as to constitute unconscionable commercial practices, in violation of UTPCPL, 73 Pa.C.S.A. § 201-1 *et seq.*

164. Plaintiff and the Class members would not have overpaid and/or paid for more Avandia prescriptions had they known of Defendants' deceptive and misleading marketing scheme, or the extent of said scheme.

165. Plaintiff and the Class members are accordingly harmed by Defendants' conduct in violation of the UTPCPL, 73 Pa.C.S.A. § 201-1 *et seq.*

166. By reason of Defendants' violations of the UTPCPL described above, Plaintiff and the Class members are entitled to recover treble damages, including but not limited to a full refund of all purchase costs Plaintiff and Class members have incurred for Avandia, in excess of what they would have spent to purchase other more effective antidiabetic drugs, plus attorney's fees and costs, along with equitable relief prayed for herein in this Complaint.

SECOND CAUSE OF ACTION

VIOLATIONS OF STATE CONSUMER PROTECTION AND UNFAIR AND DECEPTIVE ACTS OR PRACTICES STATUTES

167. Plaintiff incorporates by reference all preceding paragraphs as if fully set forth herein.

168. Defendants intended that Plaintiff, the Class and the medical and scientific community would rely on their materially deceptive practices and Plaintiff and the Class would purchase or pay for Avandia as a consequence of the deceptive practices, including Defendants' misleading and fraudulent marketing, and misrepresentations and omissions of material fact with respect to Avandia as set forth herein. Defendants' deceptive representations and material omissions to Plaintiff and the Class were and are unfair and deceptive acts and practices. Plaintiff and the Class were deceived by Defendants' misrepresentations. As a proximate result of Defendants' misrepresentations, Plaintiff and the Class have suffered an ascertainable loss, in an amount to be determined at trial, in that they paid millions upon millions of dollars for Avandia that they would not have paid had Defendants not engaged in unfair and deceptive conduct.

169. By reason of the conduct as alleged herein, by making false and misleading statements about Avandia's safety and effectiveness through false and/or misleading advertising, representations and statements with the intent to induce or cause reliance, Defendants violated the laws prohibiting unfair and deceptive acts and practices of the states wherein Class members reside.

170. Defendants engaged in unfair competition or unfair or deceptive acts or practices in violation of ALASKA STAT. § 44-1522, *et seq.*

171. Defendants engaged in unfair competition or unfair or deceptive acts or practices in violation of ARIZ. REV. STAT. § 44-1522, *et seq.*

172. Defendants engaged in unfair competition unfair or deceptive acts or practices in violation of ARK. CODE § 4-88- 101, *et seq.*

173. Defendants engaged in unfair competition or unfair or deceptive acts or practices in violation of CAL. BUS. & PROF. CODE § 17200, *et seq.*

174. Defendants engaged in unfair competition or unfair or deceptive acts or practices or make false representations in violation of COLO. REV. STAT. § 6-1-105, *et seq.*

175. Defendants engaged in unfair competition or unfair or deceptive acts or practices in violation of CONN. GEN. STAT. § 42-110b, *et seq.*

176. Defendants engaged in unfair competition or unfair or deceptive acts or practices in violation of 6 DEL. CODE § 2511, *et seq.*

177. Defendants engaged in unfair competition or unfair or deceptive acts or practices or make false representations in violation of D.C. CODE § 28-3901, *et seq.*

178. Defendants engaged in unfair competition or unfair or deceptive acts or practices in violation of FLA. STAT. § 501.201, *et seq.*

179. Defendants engaged in unfair competition or unfair or deceptive acts or practices in violation of GA. CODE ANN. §10-1-392, *et seq.*

180. Defendants engaged in unfair competition or unfair or deceptive acts or practices in violation of HAW. REV. STAT. § 480, *et seq.*

181. Defendants engaged in unfair competition or unfair or deceptive acts or practices in violation of IDAHO CODE § 48-601, *et seq.*

182. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 815 ILCS § 50511, *et seq.*

183. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ind. Code Ann. § 24-5-0.5.1, *et seq.*

184. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Iowa Code § 714.1 b, *et seq.*

185. Defendants engaged in unfair competition or unfair or deceptive acts or practices in violation of KAN. STAT. § 50-623, *et seq.*

186. Defendants engaged in unfair competition or unfair or deceptive acts or practices in violation of KY. REV. STAT. § 367.110, *et seq.*

187. Defendants engaged in unfair competition or unfair or deceptive acts or practices in violation of LA. REV. STAT. § 51:1401, *et seq.*

188. Defendants engaged in unfair competition or unfair or deceptive acts or practices in violation MASS. GEN. L. CH. 93A, *et seq.*

189. Defendants engaged in unfair competition or unfair or deceptive acts or practices in violation of MD. COM. LAW CODE § 13-101, *et seq.*

190. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of ME. REV. STAT. tit. 5, § 205-A, *et seq.*

191. Defendants engaged in unfair competition or unfair or deceptive acts or practices in violation of MICH. STAT. §445.901, *et seq.*

192. Defendants engaged in unfair competition or unfair or deceptive acts or practices in violation of MINN. STAT. § 8.31, *et seq.*

193. Defendants engaged in unfair competition or unfair or deceptive acts or practices in violation of MO. REV. STAT. § 407.010, *et seq.*

194. Defendants engaged in unfair competition or unfair or deceptive acts or practices in violation of MONT. CODE §30-14-101, *et seq.*

195. Defendants engaged in unfair competition or unfair or deceptive acts or practices in violation of NEB. REV. STAT. § 59-1601, *et seq.*

196. Defendants engaged in unfair competition or unfair or deceptive acts or practices in violation of NEV. REV. STAT. § 598.0903, *et seq.*

197. Defendants engaged in unfair competition or unfair or deceptive acts or practices in violation of N.H. REV. STAT. § 358-A:l, *et seq.*

198. Defendants engaged in unfair competition or unfair, unconscionable or deceptive acts or practices in violation of N.J. REV. STAT. § 56:8-1, *et seq.*

199. Defendants engaged in unfair competition or unfair or deceptive acts or practices in violation of N.M. STAT. § 57-12-1, *et seq.*

200. Defendants engaged in unfair competition or unfair or deceptive acts or practices in violation of N.Y. GEN. BUS. LAW § 349, *et seq.*

201. Defendants engaged in unfair competition or unfair or deceptive acts or practices in violation of N.C. GEN. STAT. § 75-1.l, *et seq.*

202. Defendants engaged in unfair competition or unfair or deceptive acts or practices in violation of N.D. CENT. CODE § 51-15-01. *et seq.*

203. Defendants engaged in unfair competition or unfair or deceptive acts or practices in violation of N.J.S.A. § 56:8-2, *et seq.*

204. Defendants engaged in unfair competition or unfair or deceptive acts or practices in violation of OHIO REV. STAT. § 1345.01, *et seq.*

205. Defendants engaged in unfair competition or unfair or deceptive acts or practices or make false representations in violation of OKLA. STAT. 15 § 751, *et seq.*

206. Defendants engaged in unfair competition or unfair or deceptive acts or practices in violation of OR. REV. STAT. § 646.605, *et seq.*

207. Defendants engaged in unfair competition or unfair or deceptive acts or practices in violation of R.I. GEN. LAWS. § 6-13.1-1, *et seq.*

208. Defendants engaged in unfair competition or unfair or deceptive acts or practices in violation of S.C. CODE LAWS § 39-5-10, *et seq.*

209. Defendants engaged in unfair competition or unfair or deceptive acts or practices in violation of S.D. CODE LAWS § 37-24-1, *et seq.*

210. Defendants engaged in unfair competition or unfair or deceptive acts or practices in violation of TENN. CODE § 47-18-101, *et seq.*

211. Defendants engaged in unfair competition or unfair or deceptive acts or practices in violation of TEX. BUS, & COM. CODE § 17.41, *et seq.*

212. Defendants engaged in unfair competition or unfair or deceptive acts or practices in violation of UTAH CODE. § 13-11-1, *et seq*

213. Defendants engaged in unfair competition or unfair deceptive acts or practices in violation of VT. STAT. ANN. TIT. 9 §2451, *et seq.*

214. Defendants engaged in unfair competition or unfair or deceptive acts or practices in violation of VA. CODE § 59.1-196, *et seq.*

215. Defendants engaged in unfair competition or unfair, deceptive or fraudulent acts or practices in violation of WASH. REV. CODE. § 19.86.010, *et seq.*

216. Defendants engaged in unfair competition or unfair or deceptive acts or practices in violation of W. VA. CODE § 46A-6-l01, *et seq.*

217. Defendant engaged in unfair competition or unfair or deceptive acts or practices in violation of WIS. STAT. § 100.18, *et seq.*

218. Defendant engaged in unfair competition or unfair or deceptive acts or practices in violation of WYO. STAT. ANN. § 40-12-101, *et seq.*

219. As a direct and proximate result of Defendants' statutory violations, Plaintiff and Class members paid for their prescriptions of Avandia, which proximately caused them injury.

220. By reason of Defendants' violations, Plaintiff and the Class members are entitled to recover treble damages where available, including but not limited to all monies expended to purchase Avandia, in excess of what they would have spent to purchase other safer, more effective, and cheaper antidiabetic drugs, plus attorney's fees and costs along with equitable relief prayed for herein in this complaint.

THIRD CAUSE OF ACTION

UNJUST ENRICHMENT

221. Plaintiff incorporates by reference all preceding paragraphs as if fully set forth herein.

222. Defendants have been and continue to be enriched by their fraudulent acts and omissions alleged herein for all states wherein class members reside.

223. In exchange for payments they made for Avandia and at the time these payments were made, Plaintiff and Class members expected that the drugs were a safe and medically effective treatment for the condition, illness, disorder or symptoms for which it was prescribed.

224. Defendants voluntarily accepted and retained these payments with full knowledge and awareness that, as a result of their wrongdoing, Plaintiff and Class members paid for Avandia when they otherwise would not have done so and paid for the drug at a higher price than would have been paid for but for Defendants' wrongful conduct.

225. These fraudulent acts and omissions allow Defendants to gain billions of dollars in profits that would not have been gained but for Defendants' fraudulent acts and omissions

226. Plaintiff and Class members and those similarly situated paid and continue to pay Defendants an amount that exceeds the value of the products identified herein as a result of Defendants' fraudulent acts and omissions.

227. Plaintiff and the Class members suffered damages due to Defendants' acts and omissions as alleged herein.

228. Defendants have and continue to be unjustly enriched as a result of their fraudulent acts and omissions.

229. Defendants lack any legal justification for engaging in a course of fraudulent acts and omissions as alleged herein at Plaintiff's and the Class' expense.

230. No other remedy at law can adequately compensate Plaintiff and Class members for the damages occasioned by Defendants' conscious choice to engage in a course of fraudulent acts and omissions.

231. Plaintiff and Class members are entitled in equity to seek restitution of Defendants' wrongful profits, revenues and benefits to the extent and in the amount, deemed appropriate by the Court and such other relief as the Court deems just and proper to remedy Defendants' unjust enrichment.

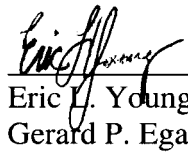
PRAYER FOR RELIEF

WHEREFORE, Plaintiff and the Class members, pray for relief as follows:

1. For an order certifying this matter as a class action as requested herein and a declaration that this action is a proper class action pursuant to Federal Rule of Civil Procedure 23, establishing an appropriate class or classes and finding that the Plaintiff and its counsel are proper representatives of the class;
2. For an Order appointing the undersigned counsel as Class counsel;
3. On Plaintiff's and the Class's claims under the Pennsylvania Unfair Trade Practices and Consumer Protection Law 73 Pa.C.S.A. § 201-1 *et seq.*, three times the damages Plaintiff and the Class have sustained as a result of Defendants' conduct, such amount to be determined at trial, plus Plaintiff's costs in this suit, including attorneys' fees;

Respectfully submitted,

EGAN YOUNG



Eric L. Young
Gerard P. Egan
526 E. Township Line Road, Suite 100
Blue Bell, Pennsylvania 19422
Phone: 215-367-5151
Fax: 215-367-5143

Douglas R. Plymale
James R. Dugan, II
Stephen B. Murray, Jr.
Stephen B. Murray, Sr.
Murray Law Firm
650 Poydras Street, Suite 2150
New Orleans, LA 70130
Phone: 504-648-0180
Fax: 504-648-0181

Counsel for Plaintiff